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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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EXAMINER

NIA, ALIREZA

ART UNIT

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,297	Applicant(s) KRESS, JURGEN	
	Examiner ALIREZA NIA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 29-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

3. The recitations "and at a side of said cover facing away from a patient" in claims 29, 47, and 48 are indefinite since the "patient" cannot be part of the claim and without the patient as a reference, it is unclear which side the openings are located. Moreover, the statement "facing away from a patient", is also unclear in the sense that, since endoscopes are used for examining body cavities, and since the cover is used in conjunction with the endoscope as a hygiene protection, when inserted into a body cavity, the cover is surrounded by the "patient" therefore, every "side" of the cover will be surrounded by the patient and all openings from the cover will be pointing/be directed at the "patient" therefore, making the above mentioned recitation indefinite and vague. Claims 29, 47, and 48 are examined as best understood.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29, 30, 32-35, 38, 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Adair 5,630,782.

6. With respect to claims 29 and 45, Silverstein discloses an endoscope 10,12, a cover 48 closed at a distal end and transmissible for optical information via 32, at least on a front face of said cover 48 via 32, and capable of being rolled in an axial direction via 48 of said endoscope 10,12 (col. 6, lines 62-65), at least one working channel 38,39 extending parallel to said endoscope 10,12 and 38 terminating in an open mode via 40,42 at said distal end 30 of said cover 48, at least one working channel 39 being connected only to said distal end 30 of said cover 48 and positioned between an outer side of said endoscope 10,12 and an inside of said cover 48, and at least one vacuum channel 36, having at least one opening 54, and terminating at said inside of said cover 48 (col. 6, lines 39-42).

7. However, Silverstein fails to positively disclose the at least one vacuum channel, having at least one opening, and terminating at a side of said cover facing away from a patient. Silverstein also fails to positively disclose the at least one working channel and said at least one vacuum channel are detachably connected to said distal end of said cover.

8. Adair teaches an analogous cover EC used to protect the insertion portion of an endoscope, the cover EC having channels 22,24 terminating at a side of the cover EC facing away (fig. 1,2) that are in communication with vacuum or fluid sources via 40-42 (col. 5, lines 10-13, lines 55-63, and col. 7, lines 1-4). Furthermore, Adair teaches channels 22,24 (working channels in S) are detachably connected to the distal end of the cover EC (col. 5, lines 23-31). Moreover, Adair further teaches the distal end of the cover EC has a wall thickness that is greater than a wall thickness of a non-distal region D of the cover EC (fig. 3) resulting in an improved

end cap that can house the distal end of the capsule of an endoscope and shield it from the sterile operating environment (col. 2, lines 38-40).

9. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope with hygiene protection of Silverstein with the structure of the channels 22,24 terminating at a side of the cover EC and the channels 22,24 being detachably connected to the distal end of the cover EC via S as taught by Adair in order to have provided an improved end cap that can house the distal end of the capsule of an endoscope and shield it from the sterile operating environment mitigating the transmission of bacteria and other harmful viruses during surgery.

10. With respect to claims 30 and 33, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches that cover 48 is of an elastomeric material (col. 7, lines 56-58) therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the elastomeric material of cover 48 would have obviously been the means for varying the cross-sectional diameter of cover 48; thus, allowing the inner diameter of cover 48 to be larger than the outer diameter of the endoscope 10,12 (col. 7, lines 56-59).

11. With respect to claim 32, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches cover 48 is flexible and elastic and foldable in an axial direction of said endoscope (col. 6, lines 62-65).

12. With respect to claims 34 and 35, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches a transparent pane or lens 32 on said distal end 30 of said cover 48 on said front face of said cover 48 (col. 6, lines 1-3, fig. 2).

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13. With respect to claim 38, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches the cover 48, when open at a proximal end, is fixable to be airtight on a shaft of said endoscope 10,12 (col. 7, lines 39-65).

14. With respect to claim 41, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches at least one vacuum channel 36 extends for at least a portion of a length of said cover 48 (col. 7, lines 1-4).

15. With respect to claim 42, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches means 54 for applying sub-atmospheric pressure to said at least one vacuum channel 36 during use of said endoscope 10,12 (col. 6, lines 39-44, col. 7, lines 26-28).

16. With respect to claim 43, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches depressions 21 in an axial direction on an outer surface of said endoscope 10,12, said depressions 21 corresponding in shape and in depth to a diameter and profile of said at least one working channel 39 and said at least one vacuum channel 36 (col. 6, lines 16-24).

17. With respect to claim 44, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches multiple U-shaped cutouts or grooves 21 to accommodate multiple channels (col. 6, lines 16-24) on the endoscope. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the U-shaped grooves 21 such that a width in the axial direction of the endoscope 12 is smaller than the width of the depression 21 at their center points in order to securely receive the channels 38, 39, and 36 onto the endoscope 12 when the cover 48 is unrolled over the endoscope.

18. With respect to claim 46, Silverstein in view of Adair disclose the invention as discussed above. Silverstein further teaches the at least one working channel 39 and said at least one vacuum channel 36 are fixed to said distal end 30 of said cover 48 (col. 6, lines 39-42).

19. With respect claims 47 and 48, Silverstein discloses an endoscope 10,12 including a cover 48 closed at a distal end 30 and transmissible for optical information via a window 32, at least on a front of said cover 48 (fig. 2), and capable of being rolled in an axial direction via 48 of said endoscope 10,12, at least one working channel 38,39 extending parallel to said endoscope 10,12 and terminating in an open mode 40,42 at said distal end 30 of said cover 48, at least one working channel 39 being connected only to said distal end 30 of said cover 48 and positioned between an outer side of said endoscope 10,12 and an inside of said cover 48 (fig. 3), and at least one vacuum channel 36, having at least one opening via 54 (col. 6, lines 39-42) terminating at said inside of said cover 48. Silverstein also discloses the use of a coating on an inner side of said window 32 at said distal end 30 of said cover 48 for producing optical contact between said window 32 and an optical channel of said endoscope 10,12 (col. 6, lines 55-57), the introduction of a distal end of said endoscope 10,12 into the cover 48, said cover 48 being open at a proximal end and closed at said distal end thereof via 32 (col. 6, line 58), rolling said cover 48 onto, or unfolding said cover 48 with, an enclosure of said endoscope 10,12 and said at least one working channel 38,39 (col. 6, lines 62-65), applying sub-atmospheric pressure to at least one said vacuum channel 36 (col. 7, lines 27-28) via 54, and fixing said at least one working channel 39 at said distal end 30 of said cover 48, said at least one working channel 38,39 being positioned in depression 21 provided on an outer surface of said endoscope 10,12 (col. 6, lines 16-24).

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20. However, Silverstein fails to positively disclose the at least one vacuum channel, having at least one opening, and terminating at a side of said cover facing away from patient.

21. Adair teaches an analogous cover EC used to protect the insertion portion of an endoscope, the cover EC having channels 22,24 terminating at a side of the cover EC facing away (fig. 1,2) that are in communication with vacuum or fluid sources via 40-42 (col. 5, lines 10-13, lines 55-63, and col. 7, lines 1-4) resulting in an improved end cap that can house the distal end of the capsule of an endoscope and shield it from the sterile operating environment (col. 2, lines 38-40).

22. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope with hygiene protection of Silverstein with the structure of the channels 22,24 terminating at a side of the cover EC as taught by Adair in order to have provided an improved end cap that is can house the distal end of the capsule of an endoscope and shield it from the sterile operating environment mitigating the transmission of bacteria and other harmful viruses during surgery.

23. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Adair 5,630,782 further in view of Sidall 4,741,326.

24. Silverstein in view of Adair disclose the invention as discussed above. However, Silverstein in view of Adair fail to positively disclose a flexible elastic sheath that prevents the contamination of an endoscope.

25. Sidall teaches a protective sheath for use with endoscopes comprising a flexible elastic sheath 1 that prevents the contamination of an endoscope (col. 3, lines 6 and 10-11) resulting in

an improved disposable protection device compatible with all endoscopes, eliminating the need for sterilization of the endoscope.

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Adair with the structure of the flexible elastic sheath 1 as taught by Sidall in order to have provided an improved disposable protection device compatible with all endoscopes while serving as a protective barrier to prevent bacterial and virus particles from coming into contact with the endoscope device, eliminating the need for sterilization of the endoscope.

27. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Adair 5,630,782 further in view of Nakao 5,217,001.

28. Silverstein in view of Adair disclose the invention as discussed above. Silverstein further discloses an end cap 112 being of rigid material mounted to a cover of elastomeric material 114 (Silverstein, col. 9, lines 40-44). Adair discloses a distal wall 36 of the cover EC that has a wall thickness greater than a wall thickness of a non-distal region D (Adair, fig. 3).

29. However, Silverstein in view of Adair fail to positively disclose the end cap to be a transparent end cap.

30. Nakao teaches a transparent end cap 24 (col. 5, line 43) used in conjunction with a disposable sheath assembly for an insertion member of an endoscope, thus resulting in an improved device for sterile endoscopic surgery by facilitating the easy introduction of surgical instruments into a patient.

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Adair with the structure of the transparent

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end cap 24 as taught by Nakao in order to have provided improved device for sterile endoscopic surgery by facilitating the easy introduction of surgical instruments into a patient.

32. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Adair 5,630,782 further in view of Adair 5,433,221.

33. Silverstein in view Adair 782 disclose the invention as discussed above. However, Silverstein in view of Adair 782 fail to positively disclose the cover to be conically enlarged in a vicinity of said proximal end with a portion of said cover being folded backwardly to be wrinkle-free in said vicinity of said proximal end and fixable via a chemically inert and non-toxic adhesive.

34. Adair 221 teaches an analogous cover 10 used in covering an endoscopic surgical camera, the cover 10 having conically enlarged in a vicinity of its proximal end 12 (the distal end 14 having a smaller diameter than proximal end 12, col. 4, lines 33-42). The cover also having a portion 20 that is folded backwardly (col. 4, lines 55-59) wherein the proximal end 12 is fixable via an adhesive 18 (col. 4, lines 50-53) resulting in an improved sterile drape for an unsterile endoscopic camera system enhancing operating room procedures.

35. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view Adair 782 with the structure of the cover 10 having the conically enlarged proximal vicinity, folded portion 20, and adhesive 18 as taught by Adair 221 in order to have an improved sterile drape for an unsterile endoscopic camera system enhancing operating room procedures by minimizing sterility problems with an apparatus of this type that requires a minimal amount of handling to be put in use.

36. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Adair 5,630,782 further in view of Darras 4,886,049.

37. Silverstein in view of Adair disclose the invention as discussed above. However, Silverstein in view of Adair fail to disclose a tear thread connected to said cover at said distal end and running parallel to said endoscope on the inside of said cover.

38. Darras discloses a tear thread 20 attached to an endoscope cover 10 (col. 3, lines 1-20) and running parallel to said endoscope on an inside of the cover 10, resulting in an improved removing means for an endoscope cover which simplifies the cleaning and sterilization of endoscopes.

39. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Adair with the structure of the cover and tear thread 20 as taught by Darras in order to have provided an improved removing means for an endoscope cover which simplifies the cleaning and sterilization of endoscopes to prevent the potential spread of viruses from one patient to another due to ineffective cleaning and sterilization of such instruments.

Response to Amendment

40. The amendments to claims 29, 47, and 48 as well as to the specification filed on December 10, 2007 are acknowledged and have been made of record.

Response to Arguments

41. Applicant's arguments with respect to claims 29-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

42. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the

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Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. N./

Examiner, Art Unit 3739

Alireza Nia

March 5th, 2008

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739